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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,807	01/17/2001	Maria Palasis	12013/58101	4398

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KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER

THANH, LOAN H

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,807

Applicant(s)

PALASIS, MARIA

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-15 and 17-27 is/are pending in the application.
- 4a) Of the above claim(s) 4, 6, 7, 11, 13, 15, 17-19, 22 and 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-10, 12, 14, 20, 21 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/15/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08/31/04</u> | 6) <input checked="" type="checkbox"/> Other: <u>Drawing filed 11/15/04</u> |

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Election/Restrictions

The requirement is still deemed proper and is therefore made FINAL.

Applicant is reminded of his election in paper 03/24/03.

Response to amendments

Claim objections have been withdrawn in view of applicant's remarks filed 11/15/04.

Information Disclosure Statement

There appears to be confusion with the IDS cited. Applicant is requested to review his records and check which PTO-1449 has been considered. Applicant has submitted to filings of IDS with no PTO-1449 forms attached. It is believed that the PTO-1449 has been already considered if the documents was only directed to US 6,146,358 and EP 0 835 673. The Examiner is considering the IDS filed 08/31/04 since it is a copy of the IDS filed 12/02/03.

Drawings

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 11/15/04 have been disapproved because they introduce new matter into the drawings. 37 CFR 1.121(f) states that no amendment may introduce new matter into the disclosure of an application. The original disclosure does not support the showing of grooves as characterized in the amended figure 5.

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The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second balloon positioned between the dilation bladder and the first balloon and the grooves in the first balloon must be shown or the feature(s) canceled from the claim(s). **No new matter should be entered.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2-3,8-10, 20-21,23, are rejected under 35 U.S.C. 102(b) as being anticipated by Crocker et al. (U.S. Patent No. 5,295,962).

Crocker et al. teach a system comprising a catheter, a source of fluid, a first inflatable balloon (32) having a measurable elasticity, and a dilatation bladder (30) having a measurable elasticity wherein the elasticity of the first balloon is greater than the dilatation bladder. Crocker et al. disclose the first balloon to be made of an elastic material such as latex located within the first balloon (32). See col. 7, lines 16-18. Further, Crocker et al. teach the dilatation bladder to be of a relatively non-elastic material. (see col. 6, lines 48-53.) and that the application of the device is to dilate a stenotic region of a body lumen as desired. (col. 6, lines 67-col. 7, line 2.) See col. 4, lines 25-29 .

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3,7-10, 12,14,20-21,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (US Patent No. 6,471,672) or Abele et al. (US Patent No. 5,704,913) in view of Sahatjian (US Patent No. 5,304,121).

Brown et al./ Abele et al. disclose a balloon catheter having dilation balloon with an inflation lumen and an outer balloon with a second inflation lumen for use in the blood vessel for angioplasty. See col. 5 and figures 1-3, and 7 of Brown et al. (See figures of Abele et al.). However, Brown et al./Abele et al. does not disclose a coated outer balloon. Sahatjian discloses a balloon catheter having a therapeutic material on the exterior surface of the balloon in the analogous art of angioplasty and balloon catheters. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the balloon catheter of Brown et al./Abele et al. with a coating as taught by Sahatjian in order to provide direct treatment of therapeutic material onto the target tissue of the blood vessel.

With respect to claim 9, they do not disclose silicone. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the materials of the balloon with silicone as a well known material used in balloon catheters, since it has been held to be within the general skill of a worker in the art to

select a known material on the basis of its suitability for the intended uses as a matter of obvious engineering choice lacking any criticality. In re Leshin , 125 USPQ 416.

Response to Arguments

Applicant's arguments with respect to claims 1-4,6,8-12,14-15,19,20-23,25 have been considered but are not persuasive.

With respect to applicant/s arguments on page 14 of the arguments filed 11/15/04, Applicant's arguments are directed at the intended use which has minimal patentable weight in a device claim. The Examiner is maintaining the rejection since the device is capable of performing the function. Crocker 's device is capable releasing the drug through the pores in an unexpanded state. When this occurs the drug will be "partially cover the balloon".

Crocker et al. teaches in column 4, lines 25-29, that the inflation can be selectively introduced with respect to applicant's amended limitation of inflating the first balloon without inflating the dilation bladder.

The Examiner is not in agreement with applicant. It appears that applicant is arguing more narrow than claimed. The first membrane is considered to be one of the balloons of Crocker.

Conclusion

This is a RCE of applicant's earlier Application No. 09/760807. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had

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been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LoAn H. Thanh
Primary Examiner
Art Unit 3763

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